

Amend claim 45 as follows:

45. A method of protecting multiple sclerosis patients against brain inflammation [inflammatory processes], comprising the administration to said patients of the composition and interferon-beta components of claim [and] 41.

Remarks

Claims 40-45 are pending in the application. Claims 40 and 42 have been provisionally rejected on an allegation of obviousness-type double patenting. Claims 41 and 43-45 are rejected under 35 USC 112(2d). Claims 40-45 are rejected as obvious over the prior art. All rejections are traversed.

Double Patenting

1. Instant claims 40 and 42 are provisionally rejected as allegedly reading on applicant's copending patent application 10/811,839 claim 42. This allegation is incorrect. Reference claim 42 recites neither olive kernel extract nor amounts of components.

2. Instant claims 40 and 42 are provisionally rejected as allegedly reading on claims 14, 16, 18, 20, 25, 31 and 36 of applicant's copending patent application 10/811,838. This allegation is incorrect. Claims 1-39 were canceled from the reference application by preliminary amendment at the time of filing.

3. Instant claims 40 and 42 are provisionally rejected as allegedly reading on claims 14, 20, 25, 31 and 36 of applicant's copending patent application 10/610,909. This allegation is incorrect. Claims 1-39 were canceled by preliminary amendment prior to examination.

4. Instant claims 40 and 42 are provisionally rejected as allegedly reading on claims 14, 20, 25, 31 and 36 of applicant's copending patent application 10/439,301. These allegations are incorrect. The cited claims in the reference also recite obligatory olive kernel extract, hexosamine SO₄, histamine-5-receptor antagonist, antagonists of CRH and UCN, hyaluronate salts, bitter willow extracts, polyunsaturated fatty acids and caffeine. Thus, it cannot be said that instant claims 40 and 42 read on the claims of the '301 application.

Applicant requests that the provisional double patenting rejections be withdrawn.

Rejections under 35 USC 112(2d)

The examiner's rejections of instant claims 41 and 43-45 have been overcome by the claim amendments kindly suggested by the examiner.

Rejections under 35 USC 103(a)

Instant claims 40-45 have been rejected as obvious over Ronca *et al* (1998) in view of Scott *et al* (1987), Gelber *et al*. (US 6,576,267), Noblie *et al*. (US 4,265,823) in light of Dr. Dukes non-peer reviewed Internet post, and in view of Welner *et al* (US 2002/0009448).

The Ronca reference was said to disclose that chondroitin sulfate is an anti-inflammatory agent. The examiner is correct.

The Scott reference was said to disclose that hydroxyzine is an anti-inflammatory agent. The examiner is correct.

The Gelber reference was said to disclose that quercetin is an anti-inflammatory agent. The examiner is correct.

The combination of Nobilie with Duke is used by the examiner to support a thesis that applicant's olive kernel extract may contain the steroid Estrol. The examiner is incorrect. First, Estrol per se is not a steroid; it is a nickname given to a large group of estrogens (see Exhibit attached). Second, the examiner presents no evidence that an Estrol or any steroid is present in olive kernel extract. Third, Duke mentions neither Estrol nor olive kernels.

The Weiner reference was said to disclose that Interferon-beta is an anti-inflammatory cytokine. The examiner is correct.

However, the examiner is incorrect in assuming that, just because a series of references shows individual elements of a claim, it would have been obvious to combine them. The references cited do not suggest such combinations. Current Federal Circuit law supports applicant's position.

In combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make the combination and (ii) a reasonable expectation that the combination would succeed. Both the suggestion and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Admittedly, some of the examiner's references disclose some of the recited elements of the claims, Yet, a focus on the parts of the invention results in improper reductionist examination. As the Federal Circuit has said: "Casting an invention as

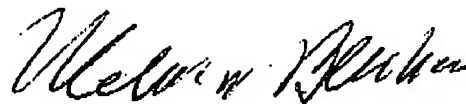
a combination of old elements leads improperly to an analysis of the claimed invention by the parts, not by the whole” *Custom Accessories Inc. v. Jeffrey-Allen Industries*, 1 USPQ2d, 1196, 1198 (Fed. Cir. 1986). Thus, the patentability of the present invention does not rest with the recitation of a single element, but rather it is the recited combination as a whole that makes up the invention that the examiner must find in the prior art in order to allege a *prima facie* case of obviousness. The applicant submits that such a case has not been established here.

The attainment of surprising results or properties is a powerful demonstration of patentability. See, *U.S. v. Adams*, 383 U.S. 39, 51-2 (1966); *Lindemann Maschinefabrik v. American Hoist and Derrick Co.*, 730 R.2d 1452, 1641 (Fed. Cir. 1984). In the present case, the unique physiological properties of olive kernel extract, both as an antioxidant and absorption promoter (see specification [028]) are evidence that applicant has demonstrated surprising results, which further establishes patentability, which must be accepted by the examiner. See, *In re Sonl*, 34 USPQ2d 1684, 1687-88 (Fed. Cir. 1995).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) the combination is improper (for example, there is a teaching away or no reasonable expectation of success); (ii) objective indicia of patentability exist (for example, unexpected results); or (iii) secondary considerations exist (for example, commercial success or long felt but unfulfilled need). See, *Graham v. John Deere Co.* 383 U.S. 1, 148 USPQ 459 (1966); *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). In the present case, the commercial success of the present invention was demonstrated in the Petition To Make Special previously filed.

It would be appropriate for the examiner to withdraw all rejections made under 35 USC 103(a).

Respectfully submitted,



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